JUN - 9 2010

Exhibit #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: k100398.

1. **Submitter's Identification:**

Standard Diagnostics, Inc.

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Contact:

Mr. Sun Young Jeong
QA/RA Manager
Standard Diagnostics, Inc.

Date Summary Prepared: June 7, 2010

2. **Name of the Device:** SmartLink™ GOLD Blood Glucose Monitoring System

3. **Common or Usual Name:** Blood Glucose Test System, Over-the-Counter

4. **Predicate Device Information:**

SD CHECK GOLD Blood Glucose Monitoring System, K082683

5. **Device Description:**

The SmartLink™ GOLD Blood Glucose System is an Rx/OTC blood glucose system to be used by professional healthcare personnel or diabetics at home to measure the glucose concentration for aiding diabetes management.

The SmartLink™ GOLD Blood Glucose System consists of a SmartLink™ GOLD Blood Glucose Meter which measures and displays test results, SmartLink™ GOLD test strip, lancet and lancing device for blood sampling, control solution to check the meter and test strip, check strip to check the meter, 3 V battery (type 2032) for power, carrying case, user guide, packaging inserts for the test strip and control solution and a Quick Guide for helping the user with a self test diary to document test results for monitoring the trend of blood glucose.

The system is a battery-operated portable device and stores 500 test results in memory. The user can search the stored results with three presentations of 7, 14 and 30-day averages of test results stored in memory: normal, pre-meal and post-meal state averages. The system can set the beep, hypo warning, date, time, post-meal alarm and alarm. The system can also set the pre-meal and post-meal mark. Test results are displayed with mg/dL unit. A check strip allows the meter to check a problem and the control solution allows the meter and test strip to be checked.

6. **Intended Use:**

SmartLink™ GOLD Blood Glucose Monitoring System is indicated for monitoring glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm or upper arm. SmartLink™ GOLD meter must be used with SmartLink™ GOLD blood glucose test strip and SD Control solutions.

The SD control solutions Level M and Level H are for use with SmartLink™ GOLD test system as quality controls to verify the accuracy of blood glucose test results.

Testing is done outside the body (in vitro diagnostic use).

This system is indicated for home (over-the-counter, OTC) by person with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. This system should not be used for the screening or diagnosis of diabetes or for testing neonates.

7. Comparison to Predicate Devices:

The SmartLink™ GOLD Blood Glucose System is substantially equivalent to our SD CHECK GOLD Blood Glucose Monitoring System, K082683 with the main difference being no coding (one code). Both the subject and predicate devices are similar in intended use and basic fundamental scientific technology with differences in:

A. SmartLink™ GOLD Meter

   Appearance, Size, Weight, Color, Codechip, PCB, LCD, MCU

B. SmartLink™ GOLD Test strip
   Printed Film, shelf life

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Based on our risk analysis evaluation results, and, in accordance with the FDA "Draft Guidance for Industry and FDA Staff - Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems, 10/24/06", outlined performance characteristics, the following testing was conducted to support the modifications found in our subject device:

- Software Verification and Validation Testing
- Precision Evaluation" (Exhibit #11)
- Linearity Testing
- Performance Evaluation at Sea Level and High Altitude
- Equipment Temperature & Humidity Exposure Test
- Mechanical Resistance to Vibration—Environmental Testing
- Document TD-8 Testing Temperature Study
- Electromagnetic Compatibility Study (EN ISO 15197:2003)
- Electrical Safety Study (IEC 61010-1 & IEC 61010-2)

None of the testing demonstrated any design characteristics that violated the requirements of the FDA recognized standards or resulted in any safety hazards. It was our conclusion that testing met all relevant standards requirements.

9. Discussion of Clinical Tests Performed:

Clinical sensitivity and clinical specificity testing is not applicable.

A system accuracy evaluation (Method Comparison with Predicate Device) for the SmartLink™ GOLD Blood Glucose Monitoring System was performed according to EN ISO 15197:2003

A user performance study was performed to demonstrate that lay consumers could obtain accurate results using the SmartLink™ GOLD Blood Glucose Monitoring System. The study was performed using capillary whole blood from fingertip, palm, forearm, and upper arm sample sites.

10. Conclusions:

Based on documentation supplied with this submission, conclusions drawn from clinical and bench testing of the subject device demonstrates that the subject device is as safe, as effective, and performs as well as our legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Standard Diagnostics, Inc.
c/o Ms. Susan Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021-1734

JUN 0 8 2010

Re: k100398
Trade/Device Name: SmartLink GOLD Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: May 7, 2010
Received: May 10, 2010

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number k100398

Device Name SmartLink™ GOLD blood glucose monitoring system

INDICATIONS FOR USE

SmartLink™ GOLD blood glucose monitoring system is indicated for monitoring glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm or upper arm. SmartLink™ GOLD meter must be used with SmartLink™ GOLD blood glucose test strip and SD Control solutions.

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Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) k100398